4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0194]

Infusion Pumps Total Product Life Cycle; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: Food and Drug Administration (FDA) is announcing the availability of the final guidance entitled, "Infusion Pumps Total Product Life Cycle; Guidance for Industry and FDA Staff." The recommendations in this guidance are intended to improve the safety and effectiveness of these devices. This guidance also describes considerations in preparing premarket submissions for infusion pumps and identifies device features that manufacturers should address throughout the total product life cycle.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Infusion Pumps Total Product Life Cycle; Guidance for Industry and FDA Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm.

5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Alan Stevens, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2561, Silver Spring, MD 20993-0002, 301-796-6294.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has evaluated a broad spectrum of infusion pumps across manufacturers and has encountered common problems with device software, human factors, reliability, and manufacturing. Based on an evaluation of reported adverse events and recalls, FDA believes that many injuries and adverse events may be avoided by improving the design verification and validation processes for infusion pump devices.

The most frequently reported infusion pump device problems are: Software error messages, human factors (which include, but are not limited to, use error), broken components, battery failure, alarm failure, over-infusion, and under-infusion. Subsequent analyses revealed that many of these design problems could be corrected during the design validation and verification processes.

The Agency believes that this guidance provides recommendations that will help mitigate observed risk and reduce potential risk associated with infusion pumps. One method of

improving the safety of infusion pumps is the inclusion of safety assurance cases as part of the premarket submissions for new, changed, or modified infusion pumps submitted by device manufacturers. This guidance explains the Agency's current thinking and provides recommendations on information to submit through the safety assurance case framework and postmarket surveillance of infusion pumps.

In April 2010, the Agency issued the special control draft guidance entitled "Draft Guidance for Industry and FDA Staff: Total Product Life Cycle: Infusion Pump--Premarket Notification [510(k)] Submissions" (Ref. 1). The Agency has reviewed the comments submitted for the 2010 guidance and has incorporated most of the recommendations in this final guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on infusion pumps. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Total Product Life Cycle: Infusion Pumps; Guidance for Industry and FDA Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive

an electronic copy of the document. Please use the document number 1780 to identify the guidance you are requesting.

IV. Paperwork Reduction Act

Under the Paperwork Reduction Act (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 803 are approved under OMB control number 0910-0437; the collections of information in 21 CFR part 801 are approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 are approved under OMB control number 0910-0073; the collections of information in 21 CFR part 822 are under OMB control number 0910-0449; the collections of information in 21 CFR 56.115 are approved under OMB control number 0910-0130; and the collections of information for safety assurance cases are approved under OMB control number 0910-0766.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at http://www.regulations.gov. (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. The FDA guidance entitled "Draft Guidance for Industry and FDA Staff: Total Product Life Cycle: Infusion Pump--Premarket Notification [510(k)] Submissions," available at http://www.fda.gov/medicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm206153.htm.

Dated: November 25, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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